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| APPLICATION NO.          | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/767,249               | 01/28/2004  | John R. Stuelpnagel  | 01-00009            | 4783             |
| 29389                    | 7590        | 05/16/2008           | EXAMINER            |                  |
| ILLUMINA, INC.           |             |                      | BAUGHMAN, MOLLY E   |                  |
| 9885 TOWNE CENTRE DRIVE  |             |                      | ART UNIT            | PAPER NUMBER     |
| SAN DIEGO, CA 92121-1975 |             |                      | 1637                |                  |
|                          |             |                      | MAIL DATE           | DELIVERY MODE    |
|                          |             |                      | 05/16/2008          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/767,249             | STUELPNAGEL ET AL.  |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Molly E. Baughman      | 1637                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 November 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 29-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 29-55 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/29/07; 12/17/07</u> .                                      | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

1. Applicant's amendments to claim 29 and addition of claim 55 in the reply filed on 11/26/07 are acknowledged.

### **Response to Arguments**

2. Applicant's arguments, see pg.6, filed 10/26/07, with respect to the rejection(s) of claim(s) 29-30,33-34,38-39,40-45, and 48-52 under 35 USC § 102(b) (Nova et al., US 6,340,588) have been fully considered, but they are not persuasive.

Applicants argued that each array location on the second substrate is “on a projection” and that the projections are dipped “into the assay well of the first substrate” overcomes the rejection of Nova et al. since Nova et al. do not teach the first and second substrate having the features as claimed as amended. This is not found persuasive because the applicants do not show how the amendments avoid the reference. Nova et al. clearly teach that the matrices with memories (i.e. second substrate comprising a plurality of discrete sites) are in the form of 96 wells or 384 well microplates or microtiter plates (see col.7, lines 49-55; col.24, lines 5-10; col.25, lines 24-28; col.77, lines 9-12; col.97, lines 59-64), which are substrates having projections (i.e. individual wells), each with a plurality of memories and such memories have different bioactive agents attached thereto (see col.14, lines 18-35, col.15, lines 8-40; col. 17, lines 8-10; col.32, lines 7-19; col. 27-60; col.36, lines 27-63; col.76; col.79, lines 65-67-col.80, lines 1-9; col.82, lines 27-37; col.96, lines 30-45; col.97, lines 37-39, 59-64; col.107, lines 14-23). Nova also teaches dipping the projections of said second

substrate into said assay wells in various embodiments (see col.106, lines 61-66 for example).

3. Applicant's arguments, see pg. 7, filed 10/26/07, with respect to the rejection(s) of claim(s) 31-31, 35-37, 45-47 under 35 USC § 103 (Nova et al., US 6,340,588 in view of Fodor et al., US 5,800,922) have been fully considered, but they are not persuasive.

Applicants argued that Nova et al. taken alone or in combination with Fodor et al. does not teach or suggest a method of detecting the presence or absence of a plurality of different analytes using a first and second substrate have the features required by the claims as amended. This is not found persuasive because the applicants do not show how the amendments avoid the references. As discussed above, Nova et al. teach the features required by the claims as amended and therefore, the rejections of Nova et al. in view of Fodor et al. stand.

4. Applicant's arguments, see pg.7-8, filed 10/26/07, with respect to the rejection(s) of claim(s) 29-51 on the ground of nonstatutory obvious-type double patenting as being unpatentable over claims 1-5 and 9 of US 6,858,394, have been fully considered, but they are not persuasive.

Applicants argued that the Office Action provides no rationale for the obviousness of a genus:species relationship. In response, claims 1 and 2 of the '394 patent recite a similar method to that of claim 29 of the instant application, with the exception of "dipping." However, the '394 patent uses "contacting" instead, which is a

broad genus, the specification of the '394 patent does discuss the embodiment of "dipping" as a species (see Fig.1A-B, and col.4, lines 12-30). Therefore, the method of the '394 patent acts as the genus and includes the species of "dipping," as defined in its specification. MPEP § 804 states, "[T]hose portion of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of the invention claimed in the patent."

5. Applicant's arguments, see pg.8, filed 10/26/07, with respect to the rejection(s) of claim(s) 29-51 on the ground of nonstatutory obvious-type double patenting as being unpatentable over claims 1-5 and 9 of US 7,060,431, have been fully considered, but they are not persuasive.

Applicants argue that the reliance of dipping at column 18 of the '431 specification as support for the species inclusion under "contacting" of claims 6 and 31 of the '431 specification is impermissible in the context of alleged double patenting. This is not found persuasive because as stated in the preceding arguments over the '394 patent, the MPEP states in chapter 804, "[T]hose portion of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of the invention claimed in the patent." The MPEP further notes that the court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of the claim," but that one can judge whether or not the invention

claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103 since only the disclosure of the invention claimed in the patent may be examined."

Therefore, the claims of the '431 patent, using the genus term "contacting," includes the species of "dipping," consistent with the specification on page.18.

**New Grounds of Rejection Necessitated by Amendment**

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
9. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al. (US 6,340,588), in view of Overbeck et al. (US 6,269,846).

The teachings of the primary reference is discussed above. This reference does not teach the method wherein the projections are used to stir said sample solutions in said assay wells.

Overbeck et al. discuss an apparatus wherein a first substrate comprises pins have pin spacing comparable with the well spacing of a 96 well plate, where the pins are dipped into the wells of the well plate (i.e. second substrate) (see col.6, lines 10-15; Fig.5-6; col.12, lines 25-34; and claims 38-42, 47). Overbeck also discusses the apparatus being configured to employ the movement of the pins in a swirling motion to effect stirring or agitation (col.14, lines 6-9).

One of ordinary skill in the art would have been motivated to modify the method of Nova et al. to use the projections to stir the sample solutions in the assay wells

because Overbeck demonstrates that devices comprising substrates that dip into assay wells of a second substrate which are configured to stir the contents of the substance contained in the assay wells were conventional in the art at the time of the invention. Overbeck demonstrates designing a device which is capable of employing a swirling movement of such projections for the added benefit of stirring or agitating the substances contained in the wells. Therefore, the skilled artisan would have had a reasonable expectation of success in also using the projections of Nova et al. in a similar manner to the pins in the device of Overbeck et al. for the added benefit of stirring or agitating the substances contained in the wells. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods and use the claimed projections for stirring therein.

### ***Summary***

10. No claims are in condition for allowance.
11. Any remaining rejections and/or objections not addressed above are withdrawn in view of the amendments and/or arguments.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Molly E. Baughman whose telephone number is (571)272-4434. The examiner can normally be reached on Monday-Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/  
Primary Examiner, Art Unit 1637

/Molly E Baughman/  
Examiner, Art Unit 1637